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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

AMERICAN REGENT, INC.,

Plaintiff,

v.

ACCORD HEALTHCARE INC.,

Defendant.

C.A. No. 2:24-cv-07791-BRM-CLW

**PLAINTIFF'S ANSWER TO
DEFENDANT'S ANSWER AND
COUNTERCLAIMS**

Plaintiff/Counterclaim Defendant American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Affirmative Defenses, and Counterclaims of Defendant/Counterclaimant Accord Healthcare, Inc. ("Accord") (ECF No. 9) as follows:

GENERAL DENIAL

ARI denies all allegations in Accord's Counterclaims except for those specifically admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges

as follows:

THE PARTIES

1. Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617.

ANSWER: On the basis of Accord's Answer to Paragraph 3 of the Complaint, ARI admits that Accord is a corporation organized and existing under the laws of North Carolina. ARI lacks information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1, and therefore denies them.

2. On information and belief, based on Counterclaim Defendant's allegation, American Regent, Inc. is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

NATURE OF THE ACTION

3. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, 35 U.S.C. § 1 et seq.

ANSWER: Paragraph 3 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Accord purports to bring these Counterclaims under the patent laws of the United States and 28 U.S.C §§ 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that these Counterclaims have merit or that Accord is entitled to any relief on its Counterclaims.

4. Counterclaimant Accord seeks a declaration that it has not infringed, is not infringing, or will not infringe, directly or indirectly, any valid and enforceable claim of United States Patent No. 11,998,565 ("the '565 patent"), literally or under the doctrine of equivalents.

ANSWER: ARI admits that Accord purports to raise Counterclaims seeking a declaration that it has not infringed, is not infringing, or will not infringe, directly or indirectly, any valid and enforceable claim of United States Patent No. 11,998,565 (the "'565 patent"),

literally or under the doctrine of equivalents. ARI denies that these Counterclaims have merit or that Accord is entitled to any relief on its Counterclaims.

5. Counterclaimant Accord also seeks a declaration that the claims of the '565 patent are invalid under one or more sections of 35 U.S.C. § 101 *et seq.*

ANSWER: ARI admits that Accord purports to raise Counterclaims seeking a declaration that the claims of the '565 patent are invalid under one or more sections of 35 U.S.C. § 101 *et seq.* ARI denies that these Counterclaims have merit or that Accord is entitled to any relief on its Counterclaims.

6. As a consequence of Counterclaim Defendant's Complaint against Counterclaimant Accord, and based on Accord's denials in its Answer, there exists an actual, continuing, and substantial case or controversy between Counterclaim Defendant and Counterclaimant Accord having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement of the '565 patent.

ANSWER: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Accord regarding Accord's infringement of the '565 patent.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Accord purports to bring these Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that these Counterclaims have merit or that Accord is entitled to any relief on its Counterclaims.

8. Counterclaim Defendant has submitted to this Court's personal jurisdiction by suing Counterclaimant Accord in this District. On information and belief, Counterclaim Defendant

sells products in this District, including the Selenious Acid products at issue in this case, and conducts substantial business in, and has regular and systemic contacts with, this District.

ANSWER: Paragraph 8 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction for purposes of this action only. ARI otherwise denies the allegations of Paragraph 8.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 9 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only. ARI otherwise denies the allegations of Paragraph 9.

BACKGROUND

10. American Regent, Inc. is the holder of New Drug Application (“NDA”) No. 209379 for Selenious Acid injection vials.

ANSWER: Admitted.

11. The ’565 patent is listed in the Orange Book for Selenious Acid.

ANSWER: Admitted.

12. The face of the ’565 patent, titled “Trace Element Compositions, Methods of Making and Use,” states that it issued on June 4, 2023.

ANSWER: Admitted.

13. Based on the face of the ’565 patent, and on information and belief, American Regent, Inc. is the assignee of the ’565 patent.

ANSWER: Admitted.

14. Accord Healthcare Inc. submitted ANDA No. 2186555 to FDA seeking approval for Selenious Acid Injection USP, 60 mcg base/mL single-dose vials; 600 mcg base/10 mL (60 mcg base/mL) Pharmacy Bulk Package (“Proposed ANDA Products”).

ANSWER: ARI admits that, by letter dated June 11, 2024, (the “Accord Notice Letter”), Accord notified ARI that Accord submitted the ANDA No. 218655 to market generic versions of

selenious acid solutions, intravenous, 60 mcg/mL and 600 mcg/10 mL. ARI otherwise denies the allegations in Paragraph 14.

15. By a letter dated June 11, 2024 (“Notice Letter”), Counterclaimant Accord notified Counterclaim Defendant of the filing of ANDA No. 219430 and that the filing contains a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each claim of the ’565 patent is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

ANSWER: ARI admits that the Accord Notice Letter notified ARI that Accord submitted ANDA No. 218655 to market a generic version of Selenious Acid Injection USP prior to the expiration of the ’565 patent. ARI further admits that the Accord Notice Letter contained arguments and/or positions that the ’565 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Accord’s factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 15.

16. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), the Notice Letter included a detailed statement of the factual and legal basis for the certification that each claim of the ’565 patent is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

ANSWER: ARI admits that the Accord Notice Letter notified ARI that Accord submitted ANDA No. 218655 to market a generic version of Selenious Acid Injection USP prior to the expiration of the ’565 patent. ARI further admits that the Accord Notice Letter contained arguments and/or positions that the ’565 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Accord’s factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 16.

17. Counterclaim Defendant filed suit on July 16, 2024, alleging that Counterclaimant Accord infringed the ’565 patent.

ANSWER: Admitted.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '565 PATENT

18. Counterclaimant Accord realleges Paragraphs 1-17 as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the '565 patent.

ANSWER: Paragraph 19 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Accord regarding Accord's infringement of the '565 patent.

20. Counterclaim Defendant has accused Counterclaimant Accord of infringing the '565 patent in connection with submission of ANDA No. 218655 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products if ANDA No. 218655 is approved.

ANSWER: Admitted.

21. The submission of ANDA No. 218655 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

22. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products pursuant to ANDA No. 218655 would not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

23. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '565 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

ANSWER: Denied.

24. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 218655 to FDA does not infringe any valid and enforceable claim of the '565 patent.

ANSWER: Denied.

25. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '565 patent.

ANSWER: Denied.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '565 PATENT

26. Counterclaimant Accord realleges Paragraphs 1-25 as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

27. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '565 patent.

ANSWER: Paragraph 27 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Accord regarding Accord's infringement of the '565 patent.

28. The '565 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, including for the reasons stated in Accord's Notice Letter and Detailed Statement, and/or for obviousness type double patenting.

ANSWER: Denied.

29. Counterclaimant Accord is entitled to a judicial declaration that the '565 patent is invalid.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Accord is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (A)–(H) of Counterclaimant Accord’s Prayer for Relief.

Each averment and/or allegation contained in Accord’s Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Accord’s Counterclaims with prejudice, awarding ARI’s attorneys’ fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: September 3, 2024

Of Counsel:

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American Regent, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2024, copies of the foregoing **PLAINTIFF'S ANSWER TO DEFENDANT'S ANSWER AND COUNTERCLAIMS** were caused to be served on counsel of record via email and CM/ECF.

Date: September 3, 2024

s/ Charles H. Chevalier
Charles H. Chevalier